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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/028,396	12/21/2001	Danny Huylebroeck	2676-5174US	3530

24247 7590 03/12/2004

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EXAMINER	
RAWLINGS, STEPHEN L	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 03/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/028,396	HUYLEBROECK ET AL.	
	Examiner	Art Unit	
	Stephen L. Rawlings, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *7-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Notice to Comply*.

DETAILED ACTION

1. The election with traverse filed November 10, 2003 is acknowledged and has been entered. Applicant elected Group I, claims 1-6, insofar as the claims are drawn to a process for identifying transcription factors and a transcription factor identified by said process, wherein said process comprises providing cells with a nucleic acid sequence comprising CACCT-N-CACCT.

2. The amendment filed November 10, 2003 is acknowledged and has been entered. Claims 1 and 13 have been amended. Claim 18 has been added.

3. Claims 1-18 are pending in the application. Claims 7-17 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the response filed November 10, 2003.

4. Claims 1-6 and 18, insofar as the claims are drawn to the elected invention, are currently under prosecution.

Election/Restrictions

5. Applicant's traversal of the restriction and election requirement set forth in the Office action mailed October 23, 2003 is acknowledged. Applicant has argued the restriction and election requirement is improper because the present invention relates in essence to the DNA binding place of specific zinc finger proteins. Applicant has remarked it appears the requirement to select a single one of the sequences recited in the claims treats four configurations of the same molecule as if it were four different molecules. Applicant has argued that because the four different sequences do not encode different proteins, but instead represent different possible configurations of the same molecule, the inventions of groups I-IV are not materially different methods. Applicant has further remarked the MPEP states that normally ten sequences constitute

a reasonable number for examination. In addition, it is noted that Applicant has argued claims 2-6 and 18 should be considered linking claims.

Applicant's arguments have been carefully considered but not found persuasive for the following reasons:

The claims are drawn to materially different methods, because the claims recite the step of providing a cell comprising distinct nucleic acid molecules comprising different nucleotide sequences. The different nucleotide sequences to which the claims refer do not encode proteins, but represent different elements of a promoter or enhancer, which might function to regulate the transcription of an unspecified gene comprising such a promoter or enhancer; however, the different sequences are not representative of different configurations of any one DNA molecule. Therefore, contrary to Applicant's remarks, the present invention does not relate in essence to the same nucleic acid molecule in different configurations; nor does the invention relate in essence to the binding site of any particular DNA binding protein, or moreover any specific zinc finger protein. Rather the claims appear to be drawn to a method for identifying members of a genus of transcription factors, including activators and repressors, which bind one of the different nucleic acid molecules described by the claims. MPEP § 803 provides for proper restriction where the multiple claimed inventions are distinct or independent and where searching more than one invention would constitute a serious burden. At least because the methods are materially different the inventions are distinct. Therefore, because the search required to examine any one invention is not co-extensive with the search required to examine any other, the restriction is proper. In reply to Applicant's remark that up to ten sequences can be searched, where multiple inventions drawn to different sequences are claimed, the Office does not presently have the resources necessary to search more than one sequence.

In reply to Applicant's remarks suggesting claims 2-6 and 18 are linking claims, claim 1 is presently the only linking claim pending in the application and under prosecution. MPEP § 809.03 defines a linking claim as a claim, which is inseparable from claims to two or more otherwise properly divisible inventions. In this instance,

claim 1 is a linking claim because claim 1 is a genus-type claim linking species-type claims 2 and 18, which are each drawn to multiple and properly divisible inventions. Claim 1 is also a linking claim because claim 1 is drawn to the necessary process for making product of claim 6, such that claims 1 and 6 are linked. Upon allowance of the generic or linking claim, the restriction and election requirement shall be withdrawn, even where claims to non-elected linked inventions have been canceled, and any claims depending from or otherwise including all the limitations of the allowable linking claim will be entitled to examination in the instant application. However, contrary to Applicant's remarks, none of claims 2-6 and 18 are linking claims. Claims 2 and 18 are Markush-type claims, which encompass a plurality of distinct inventions, but claims 2 and 18 are not generic. The reasons the inventions are distinct have been set forth above. MPEP § 803.02 states it is proper to restrict Markush-type claims drawn to a plurality of distinct inventions unity of invention, unless the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden. For the reasons set forth above, a search and examination of the multiple distinct inventions cannot be made without serious burden. Furthermore, MPEP § 803.02 states it is proper to restrict Markush-type claims drawn to a plurality of distinct inventions unity of invention, if the subject matter in the Markush-type claims lacks unity of invention. Broadly, unity of invention exists where members included within a Markush group (1) share a common utility, **and** (2) the materials used share a substantial structural feature disclosed as being essential to that common utility. In this instance, claims 2 and 18 are drawn to methods, which do not share a common utility, because the utility of each distinct invention differs in that each provides a process for identifying transcription factors, which bind to nucleic acid molecules comprising *different* sequences. Accordingly, the subject matter encompassed by claims 2 and 18 lacks unity of invention.

The restriction and election requirement is made FINAL.

Information Disclosure Statement

6. The information disclosure filed December 21, 2001 has been considered in part, as it appears only the first of two pages of the information disclosure statement has been submitted. Any information disclosed by a second page of the statement filed December 21, 2001 cannot have been considered. An initialed copy of the first page of the statement is enclosed.

Sequence Rules Compliance

7. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

As noted on the attached Notice to Comply, sequences are depicted in Figure 1, which are not properly identified by sequence identification numbers but which are of sufficient length to fall under the requirements set forth under 37 CFR §§ 1.821-1.825. As noted in the attached Notice to Comply, appropriate action correcting this deficiency is required.

Applicant is given the same period of time within which to reply to this Office action to comply with the sequence rules under 37 C.F.R. §§ 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R. § 1.821(g).

Specification

8. The specification is objected to because the use of numerous improperly demarcated trademarks has been noted in this application. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks. See MPEP § 608.01(v).

Examples of improperly demarcated trademarks include QuikChange™ (page 43), TopCount™ (page 44), and Hybond™ (page 45).

Appropriate corrections are required. Each letter of a trademark should be capitalized or otherwise the trademark should be demarcated with the appropriate symbol indicating its proprietary nature (e.g., ™, ®), and accompanied by generic terminology. Applicants may identify trademarks using the "Trademark" search engine under "USPTO Search Collections" on the Internet at http://www.uspto.gov/web/menu/search.html.

9. The specification is objected to because of the following informality: "QuikChange™" is misspelled at page 43. Appropriate correction is required.

10. The abstract is objected to because of multiple omissions of the number of the disclosed SEQ ID NOs. Appropriate correction is required.

Claim Objections

11. Claims 1-6 and 18 are objected to because the claims are drawn in the alternative to the subject matter of non-elected inventions.

Claim Rejections - 35 USC § 101

12. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

13. Claim 6 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 6 is drawn to a transcription factor produced by the process of claim 1.

Claim 6 encompasses a transcription factor contained within a cell, for example, which is a naturally occurring product. Such a naturally occurring transcription factor

cannot be distinguished from the presently claimed transcription factor produced by the process of claim 1.

Amending claim 6 to recite, for example, the term "isolated" or "purified" before "transcription factor" can obviate this rejection.

Claim Rejections - 35 USC § 112

14. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15. Claim 6 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 6 is a "reach-through" claim drawn to a transcription factor produced by the process of claim 1. Claim 6 encompasses a genus of transcription factors, which are *yet to be* identified or described. The structures and functions of the as yet to be identified or described members of the genus of transcription factors cannot be immediately envisioned or even predicted. In fact, the structures and functions of the members of the claimed genus can only be determined empirically. Moreover, the members of the claimed genus are expected to have widely varying structures and functions, as the members may bind to entirely different nucleotide sequences and thereby regulate the transcription of entirely different genes. Applicant has not set forth a description of at least a substantial number of members of the claimed genus, nor has Applicant described a representative member of the genus by describing such a member as having a characteristic feature that is common to at least a substantial number of the members. As such the specification would not reasonably convey to the

skilled artisan that Applicant had possession of the claimed invention at the time the application was filed.

MPEP § 2163.02 states, "[a]n objective standard for determining compliance with the written description requirement is, 'does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed' ". The courts have decided:

> The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the "written description" inquiry, *whatever is now claimed.*

See *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Federal Circuit, 1991). Furthermore, the written description provision of 35 USC § 112 is severable from its enablement provision; and adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

The Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, paragraph 1, ``Written Description" Requirement (66 FR 1099-1111, January 5, 2001) state, "[p]ossession may be shown in a variety of ways including description of an actual reduction to practice, or by showing the invention was 'ready for patenting' such as by disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention" (*Id.* at 1104). Moreover, because the claims encompass a genus of variant species, an adequate written description of the claimed invention must include sufficient description of at least a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics sufficient to show that Applicant was in possession of the claimed genus. However, factual evidence of an actual reduction to practice has not been disclosed by Applicant in the specification; nor has Applicant shown the invention was "ready for patenting" by disclosure of drawings or

structural chemical formulas that show that the invention was complete; nor has Applicant described distinguishing identifying characteristics sufficient to show that Applicant were in possession of the claimed invention at the time the application was filed.

16. Claim 5 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 5 is drawn to a process for identifying transcription factors comprising providing cells having a nucleic acid sequence originating from a promoter region of the genes encoding Brachyury, α4 integrin, follistatin, or E-cadherin, which comprises the sequence CACCTG-N-CACCTG, where N is a nucleotide sequence according to the specification at page 5, paragraph 0010. The promoter regions of the genes encoding Brachyury, α4 integrin, follistatin, and E-cadherin have not been reported to comprise the sequence CACCTG-N-CACCTG, where N is a nucleotide sequence according to the specification at page 5, paragraph 0010, and there is no factual evidence of record suggesting otherwise. Accordingly, the claimed method cannot be practiced because the nucleic acid sequence comprising CACCTG-N-CACCTG cannot be originated from the promoter regions of the genes encoding Brachyury, α4 integrin, follistatin, or E-cadherin.

17. Claim 6 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 6 is a "reach-through" claim drawn to a transcription factor produced by the process of claim 1. Claim 6 encompasses a genus of transcription factors, which are *yet to be* identified or described. The structures and functions of the as yet to be

identified or described members of the genus of transcription factors cannot be immediately envisioned or even predicted. In fact, the structures and functions of the members of the claimed genus can only be determined empirically. Accordingly, one skilled in the art cannot make or use the claimed invention with a reasonable expectation of success without the need to perform an additional and undue amount of experimentation to first identifying the transcription factor, producing the transcription factor, characterizing the function of the transcription factor, and then elaboration a use for the transcription factor.

18. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

19. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 is indefinite because claim 6 recites, "produced by the process of claim 1", where claim 1 is drawn to a method for *identifying* transcription factors. Notably claim 1 does not comprise any process steps by which the transcription factor is produced. As a result, the metes and bounds of claim 6 are ambiguous and accordingly claim 6 fails to meet the requirements set forth under 35 USC § 112, second paragraph.

Claim Rejections - 35 USC § 102

20. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

21. Claim 6 is rejected under 35 U.S.C. 102(b) as being anticipated by Genetta et al. (*Mol. Cell. Biol.* **14**: 6153-6163, 1994).

Genetta et al. teaches a transcription factor designated ZEB, which is a "two-handed" zinc finger protein, which binds to a DNA enhancer having a set of E boxes, which comprises two E boxes having the sequence CACCTG separated one from the other by an intervening nucleotide sequence.

The product of the prior art and the claimed product are deemed the same because claimed product would necessarily bind to a nucleic acid molecule comprising the sequence CACCTG-N-CACCTG, where N is a nucleotide sequence according to the specification at page 5, paragraph 0010, and Genetta et al. teaches ZEB binds an enhancer having a set of E boxes having the sequence CACCTG, which are separated by a nucleotide sequence N, according to the specification at page 5, paragraph 0010.

Although Genetta et al. does not teach the process of claim 1 produced the disclosed transcription factor, the patentability of a product does not depend upon its method of production. See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985). See MPEP § 2113.

22. Claim 6 is rejected under 35 U.S.C. 102(b) as being anticipated by Sekido et al. (*Genes Cells.* **2**: 771-783, 1997).

Sekido et al. teaches a transcription factor designated δEF1, which comprises two clusters of zinc fingers. Sekido et al. teaches the transcription factor binds to a DNA enhancer having a set of E boxes, which comprises two E boxes having the sequence CACCTG separated one from the other by an intervening nucleotide sequence.

The product of the prior art and the claimed product are deemed the same because claimed product would necessarily bind to a nucleic acid molecule comprising the sequence CACCTG-N-CACCTG, where N is a nucleotide sequence according to the specification at page 5, paragraph 0010, and Sekido et al. teaches δEF1 binds an enhancer having a set of E boxes having the sequence CACCTG, which are separated by a nucleotide sequence N, according to the specification at page 5, paragraph 0010.

Although Sekido et al. does not teach the process of claim 1 produced the disclosed transcription factor, the patentability of a product does not depend upon its method of production. See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985). See MPEP § 2113.

Claim Rejections - 35 USC § 103

23. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

24. Claims 1-4, 6, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mak et al, (*DNA Cell Biol.* **15**: 1-8, 1996) in view of Sekido et al. (*Genes Cells.* **2**: 771-783, 1997).

Claims 1-4 are drawn to a process for identifying transcription factors, including activators and repressors, said process comprising providing cells having a nucleic acid sequence comprising CACCT-N-CACCT, which sequence can be used as bait to screen a library encoding potential transcription factors. "N" of the sequence CACCT-N-CACCT is defined at page 5 of the specification to be a nucleotide sequence separating the two CACCT sequences by a number of nucleotide residues, which number ranges from 0 to at least 400. Claim 3 requires the transcription factor to comprise separated clusters of zinc fingers. Claim 4 requires the sequence used as bait to originate from a promoter region. Claim 6 is drawn to a transcription factor produced by the process of claim 1. Claim 18 is drawn a process for identifying transcription factors, including activators and repressors, said process comprising providing cells having a nucleic acid sequence comprising at least two copies of the CACCT-N-CACCT sequence, which sequence can be used as bait to screen a library encoding potential transcription factors.

Mak et al. teaches a method by which mammalian cDNA libraries can be screened to isolate cDNA molecules encoding novel transcription factors that interact with E-box sites. Mak et al. discloses the E-box site has the consensus sequence CANNTG, where N is A, C, T or G. The method of Mak et al. utilizes an E-box *HIS3* reporter, which is an expression plasmid comprising multiple E-box sites, which are used as bait in screening the cDNA library to identify the transcription factors that bind those sites.

However, Mak et al. does not expressly disclose the E-box site can be a sequence comprising CACCT; nor does Mak et al. teach a cell having a nucleic acid sequence comprising two E-box sequences of CACCT separated by a nucleotide sequence ranging in length from 0 to at least 400, which nucleic acid sequence can be used as bait. In addition, Mak et al. does not expressly teach the disclosed method can be used to identify transcription factors comprising separated clusters of zinc fingers, as required by claim 3.

Sekido et al. teaches an enhancer DNA sequence, which originates from the promoter region of a gene encoding δ1-crystallin. The enhancer DNA sequence comprises two E-box sequences of CACCT separated by a nucleotide sequence ranging in length from 0 to at least 400. Sekido et al. teaches transcription factors, including activators and repressors bind to the enhancer sequence. In particular, Sekido et al. teaches δEF1, which comprises two clusters of zinc fingers, binds to the enhancer DNA sequence. Sekido et al. teaches production of δEF1 and mutants thereof, which are used to characterize the activity of δEF1.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of invention to practice the method of Mak et al. using the enhancer disclosed by Sekido et al. as bait to screen a cDNA library to identify novel transcription factors, which bind the enhancer sequence, because Sekido et al. teaches the enhancer sequence comprises E-box sites to which transcription factors, including activators and repressors bind and because Sekido et al. teaches the transcription factor, which binds the enhancer sequence, can comprise clusters of zinc fingers. One of ordinary skill in

the art at the time of invention would have been motivated to do so to identify novel transcription factors, which bind to the enhancer and regulate the transcription of the gene encoding δ1-crystallin.

Furthermore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of invention to produce a transcription factor encoded by the cDNA molecule selected by the screening process, because Sekido et al. teaches production of transcription factors encoded by isolated cDNA molecules. One of ordinary skill in the art at the time of invention would have been motivated to do so, because Sekido et al. teaches the transcription factor and mutants thereof can be used to characterize the activity of transcription factor.

Conclusion

25. No claims are allowed.

26. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. Li et al. (*Science* **262**: 1870-1874, 1993), Luo et al. (*Biotechniques* **20**: 564-568, 1996), and Remacle et al. (*Nucleic Acids Res.* **26**: 5223-5224, 1998) teach one-hybrid systems for screening cDNA libraries to identify transcription factors. Blaiseau et al. (*Mol. Cell. Biol.* **17**: 3640-3648, 1997), Susuki et al. (*J. Biochem.* (Tokyo) **124**: 389-395, 1998), and Houchens et al. (*Nucleic Acids Res.* **28**: 570-581, 2000) teach isolating a cDNA encoding a transcription factor comprising a cluster or clusters of zinc fingers using a yeast one-hybrid system. U.S. Patent No. 6,313,2809 B1 teaches a nucleic acid molecule encoding the polypeptide of SEQ ID NO: 1, which is the transcription factor SIP1. Verschueren et al. (*J. Biol. Chem.* **274**: 20489-20498, 1999) teaches the transcription factor SIP1.

27. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne (Bonnie) Eyler, Ph.D. can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1642

slr
February 24, 2004

/YVONNE EYLER, PH.D/
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600